U. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Date: February 19, 2013
Chemical: Cyantraniliprole
PC Code: 090098
DP Barcodes: 392834, 400297
DECISION: 451670

MEMORANDUM

SUBJECT: EFED Environmental Risk Assessment of Proposed New Global Chemical Cyantraniliprole on Bushberries, Citrus, Cotton, Oil Seeds, Pome Fruit, Stone Fruit, Tree Nuts, Vegetables (Bulb, Corm and Tuberous, Cucurbit, Fruiting, Leafy Brassica, and Leafy-Non-Brassica), and Professional Products (Fly Bait, Indoor and Outdoor Insect Control for Public Health Pests Such as Cockroaches, Ants, Flies, Termites, Nuisance Insect Pests, Turfgrass and Ornamentals, Tree Injection, and Production Greenhouse and Nursery Ornamentals)

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The Environmental Fate and Effects Division (EFED) has assessed the ecological risks to federally listed threatened/endangered (hereafter referred to as "listed") and non-listed species associated with the proposed uses of the new global insecticide, cyantraniliprole. The uses are far reaching and cover both agricultural crops (*e.g.*, leafy vegetables,

bushberries, tuberous and corm vegetables), as well as residential and forestry uses (*e.g.*, ornamentals, trees, public health pests). Application methods are equally diverse; cyantraniliprole is applied via foliar spray (ground and aerial), bark spray, soil injection, soil drench, in-furrow, knifing, shanking, drip chemigation, micro spray chemigation, seed treatment, and spot, crack and crevice spray. Maximum application rates range from 0.016 to 0.69 lb ai/A, with seasonal maximums up to 0.69 lb ai/A. EFED used a number of modeling scenarios to evaluate cyantraniliprole's potential exposure of non-target organisms, both through standard (spray drift, runoff) and systemic routes.

No direct risks from the proposed uses of cyantraniliprole were identified for the following:

- Birds, reptiles, and terrestrial-phase amphibians (acute and chronic)
- Mammals (acute)
- Freshwater Invertebrates (chronic)
- Aquatic plants
- Freshwater fish and aquatic-phase amphibians (acute and chronic)
- Estuarine/marine fish (acute)
- Estuarine/marine invertebrates (chronic)
- Terrestrial plants (dicots)

Seven groups were identified as being at direct risk from the use of cyantraniliprole:

- Terrestrial invertebrates (acute)
- Mammals (chronic)
- Freshwater invertebrates (acute)
- Estuarine/marine invertebrates (acute)
- Benthic invertebrates (acute and chronic)
- Estuarine/marine fish (chronic)
- Terrestrial plants (monocots)

The following sections summarize the major conclusions regarding these groups.

Terrestrial Invertebrates

- Risk quotient analysis indicates proposed cyantraniliprole products present a potential risk to individual honeybees (*Apis mellifera*).
- Semi-field studies indicate increased mortality, intoxication, and repellency effects on adult forage bees for up to six days after application (representing a potential reduction in pollinator services).
- Measured concentrations of cyantraniliprole in food sources (pollen and nectar) were lower (except for guttation fluid) than acute toxicity values for honeybees for rates of up to 0.134 lb ai/A (foliar spray) and 0.089 lb ai/A (drip chemigation); data were not available for higher labeled rates (up to 0.69 lb ai/A single maximum application rate).
- Risk quotients calculated for cyantraniliprole residues on food items (pollen and honey) indicate potential risks to individual honeybees through dietary exposure at rates up to 0.134 lb ai/A; data were not available for higher rates.

- Semi-field studies indicate low likelihood for long-term honeybee hive effects for cyantraniliprole-only products up to 0.134 lb ai/A (foliar spray). Field data were not available for higher labeled rates.
- Semi-field studies indicate a potential increase in honeybee susceptibility to *Varroa* mites (*Varroa destructor*) following exposure to cyantraniliprole.
- Potential exposures to dust from cyantraniliprole-treated seed or harvesting cyantraniliprole-treated crops were not assessed and remain an uncertainty.
- Toxicity data for cyantraniliprole-thiamethoxam products indicate potential risk to honeybees; no field studies were available to verify risks.
- Spray drift buffers to protect listed species from potential acute risks range from 607 to >1000 ft (cyantraniliprole-only products) and >1000 ft (cyantraniliprole-thiamethoxam products).

Mammals

- Risk quotient analysis indicates proposed cyantraniliprole uses present potential chronic risk to mammals; the exceptions are uses on non-woody potted ornamental plants, and the seed treatments (potato, rapeseed/mustard seed, and sunflower).
- Mammals that consume short grass, tall grass, broadleaf plants, and arthropods are potentially at direct risk (based on EECs); risk is not expected for mammals with seeds/fruits, and/or pod diets.
- Chronic effects at the lowest observed adverse effect level (LOAEL = 200 ppm) include thyroid weight increase and corresponding dose-related increase in the incidence of thyroid follicular epithelial cell hypertrophy/hyperplasia in adult rats.
- Offspring chronic effects (LOAEL = 2000 ppm) include decreases in organ weights (thymus, spleen, brain, and adrenal gland) and pup body weight.

Freshwater Invertebrates

- Risk quotient analysis indicates most of the proposed cyantraniliprole uses present potential acute risks to freshwater invertebrates.
- The cyantraniliprole-thiamethoxam products are more acutely toxic to freshwater invertebrates than cyantraniliprole-only products.
- Spray drift buffers to protect listed species from potential acute risks range from 0 to 197 ft for cyantraniliprole-only products and 10 to >1000 ft for cyantraniliprole-thiamethoxam products.

Estuarine/Marine Invertebrates

- Risk quotient analysis indicates that the proposed cyantraniliprole uses for cotton (aerial and ground), cucurbits (aerial and ground), and fruiting vegetables (aerial) present potential acute risks to estuarine/marine invertebrates.
- The highest RQ is 0.072; slightly reducing application rates would eliminate the risk.
- Based on AgDRIFT no spray drift buffer is required to protect listed species.

Benthic Invertebrates

- Risk quotient analysis indicates acute risk to benthic invertebrates from one cyantraniliprole use – seed treatment for rapeseed/mustard seed; chronic risks were identified for approximately half of the uses.
- The acute risk quotient for rapeseed/mustard seed is 0.051; slightly reducing the rate would eliminate the risk concern.

Estuarine/Marine Fish

- Potential risks to listed estuarine/marine fish are based on non-definitive data.
- The fish early life-stage test showed effects at the lowest concentration tested, thus yielding a non-definitive (less than) NOAEC.
- Defining the NOAEC with another chronic estuarine/marine fish study may eliminate risk concerns.

Terrestrial Monocots

- Potential risks to listed monocotyledonous (monocot) plants are based on an absence of seedling emergence data.
- The most sensitive monocot for the vegetative vigor test is onion, but seedling emergence data are not available for this species.
- If the onion NOAEC is slightly more toxic ($\leq$ 0.100 lb ai/A) than the current most sensitive seedling emergence endpoint (0.134 lb ai/A), risk quotients will exceed the LOC for monocots.

Indirect effects are expected for any species that depends on terrestrial invertebrates, terrestrial monocots, estuarine/marine fish, mammals, or aquatic invertebrates for food, habitat, or other environmental resources.

The following data gaps were identified in this risk assessment:

Environmental Fate:

- **Analytical Method for the Determination of DPX-HGW86 in Air Using LC/MS/MS (MRID 48119930)**: No Independent Laboratory Validation (ILV) was provided for this study.

Ecological Effects:

- **Chronic Toxicity to Estuarine/Marine Invertebrates (850.1350):** Data were not available for the chronic toxicity to an estuarine/marine invertebrate species. In lieu of this, the acute-to-chronic ratio method was used to estimate a chronic toxicity value for the Eastern oyster (*Crassostrea virginica*) the most sensitive estuarine/marine invertebrate on an acute basis.

- **Estuarine/Marine Fish Early Life-Stage (850.1400):** The current early-life stage study for estuarine/marine fish presents a non-definitive NOAEC (less than value). Without a definitive lower bound on cyantraniliprole's toxicity, chronic risk concerns for estuarine/marine fish cannot be precluded.

- **Field Testing for Pollinators (850.3040):** Multiple semi-field studies are available for cyantraniliprole; however, these tests were conducted up a single maximum application rate of 0.134 lb ai/A; whereas the maximum single application rate for some uses is up to 0.69 lb ai/A. There is uncertainty regarding the effects to honeybee hive health and pollination services at single application rates above 0.134 lb ai/A. If performed, the test should 1) occur on a crop that is attractive to bees, 2) be applied at bloom and/or 3) be applied where bees are likely to be foraging.

- **Larval Honeybee Toxicity Test (Non-Guideline Study):** Given that cyantraniliprole is highly toxic to adult honeybees on an acute exposure basis, a larval toxicity test would provide information on the acute toxicity to larvae. Food type and consumption rates differ from adults and larvae could be more or less sensitive to cyantraniliprole and/or experience different exposure routes than adults. In the absence of this study, information from the semi-field studies may be used to extrapolate the effects of cyantraniliprole on larvae (in terms of long-term brood effects).

- **Seedling Emergence Test (850.4100):** Only a partial set of acceptable data were available for this test (corn, cucumber, oilseed rape, soybean, and sugar beet). The assessment relied on the five species that were tested, but there is uncertainty whether the most sensitive monocot was tested (onion was the most sensitive in the vegetative vigor test, but seedling emergence data are not available for onion) A seedling emergence test should be conducted with three other species of monocots (including onion) and two other species of dicots. In the absence of a complete set of data, the results from the partial set (1 monocot, 4 dicots) were used.

Labeling Recommendations

The following statements are taken from the Label Review Manual:

- Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas.
- This pesticide is toxic to mammals.
- This pesticide is toxic to aquatic invertebrates.
- This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

In addition, the following refinements should be considered:

- To reduce the potential for direct effects on foraging adult bees, applications should be conducted during time periods of minimal bee foraging activity (*e.g.*, before 7 am and after 7 pm).
- To reduce exposure and potential risks resulting from consumption of contaminated pollen and nectar, applications should avoid periods of bloom for labeled crops. This would include crop-specific label restrictions based on the

blooming window for each applicable crop. Consideration would also need to be given to the time required for cyantraniliprole to dissipate in applicable plant tissues following its application and subsequent translocation in plants.

- Requiring buffers of up to 200 ft for foliar applications would reduce potential acute risks from spray drift to freshwater invertebrates. This is applicable to the cyantraniliprole-only products; cyantraniliprole-thiamethoxam product buffers would need to be >1000 ft.
- Registering rates up to a single maximum application rate of 0.134 lb ai/A. This is the highest rate tested in the honeybee field studies and eliminates the uncertainties surrounding adverse effects at higher application rates for pollinators.

Response to Comments

The Agency received a public comment regarding the evaluation of cyantraniliprole for registration in the United States (DP 400297). The San Francisco Bay Regional Water Quality Control Board requested that EPA:

"*...carefully evaluate all cyantraniliprole product registration applications. Specifically, we request a full evaluation of the potential for cyantraniliprole products to cause adverse impacts in the water column and/or sediments in California's urban waterways. We request that EPA consider all urban application locations and evaluate potential pathways to receiving waters under conditions consistent with label instructions. The evaluation should include stable degradates and the time required for the active ingredient to become non-toxic in the environment. If use of the pesticide consistent with the label instructions can result in toxicity in the receiving water, further restrictions on use must be evaluated. We encourage EPA to pay special attention to application types – like control of insects around buildings and pre-construction termiticide applications – that are being addressed in EPA's pyrethroid Registration Reviews.*"

EFED has addressed this comment by employing the Total Toxic Residue approach in its evaluation of cyantraniliprole and its degradates in aquatic systems. In cases where risk concerns to aquatic organisms were identified, EFED explored mitigation options through buffers (AgDRIFT analysis) and recommended application rate reductions, where appropriate.